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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,705	09/11/2003	A. Thomas Look	112706.123US2	6046
24395	7590	05/18/2006	EXAMINER	
WILMER CUTLER PICKERING HALE AND DORR LLP 1875 PENNSYLVANIA AVE., NW WASHINGTON, DC 20004			BERTOGLIO, VALARIE E	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/659,705	LOOK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-74 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-24, 31-36-39 and 67-74 drawn to a transgenic fish whose genome comprises an oncogene operably linked to a promoter and a method using the fish to screen for drugs, classified in class 800, subclass 20.
- II. Claims 25-30 and 60-66, drawn to a transgenic fish whose genome comprises an FRT-flanked reporter gene and oncogene operably linked to a ubiquitous promoter wherein a transcriptional stop codon is inserted between the reporter gene and oncogene a method using the fish to screen for drugs, classified in class 800, subclass 20.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because they are structurally distinct fish requiring different methods of making and using. The fish of Invention II require different technical considerations and methodologies as the transgene is constructed to be controlled using a different mechanism. The fish of Invention II comprises a ubiquitously expressed transgene wherein transcription of the oncogene is inhibited prior to cell-specific heat-shock or other cell-specific expression of a site-specific recombinase. The fish of Invention I uses a cell-specific gene promoter to control gene expression.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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1) This application contains claims directed to the following patentably distinct species:

- A) keratin-8,
- B) islet-1,
- C) PDX-1,
- D) insulin,
- E) GFAP,
- F) MYO-D,
- G) alpha-actin,
- H) tyrosine hydroxylase,
- I) MPO,
- J) PU-1
- K) RAG1
- L) RAG2
- M) CD2.

The species are independent or distinct because each promoter will drive expression of a transgene in different cells or tissues, resulting in fish with different structure, function and uses.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-7,9-23,31-34,36-42,44-58,66-73 are generic.

2) This application contains claims directed to the following patentably distinct species:

- A) MYC,
- B) CYCLIN D1,

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- C) FOS,
- D) JUN,
- E) MYB,
- F) BCL-2,
- G) HOX11,
- H) HOX11L2,
- I) TAL1/SCL,
- J) LMO1,
- K) LMO2,
- L) MYCN,
- M) MDM2,
- N) CDK4,
- O) GLI1,
- P) IGF2,
- Q) activated RAS,
- R) activated EGFR,
- S) mutated FLT3-ITD,
- T) mutated TP53,
- U) activated TP53,
- V) PAX3,
- W) PAX7,
- X) BCR/ABL,

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Y) HER2/NEU,

Z) FLT3R,

AA) NPM-ALK,

BB) SRC,

CC) RAS,

DD) ABL,

EE) TAN1,

FF) PTC,

GG) B-RAF,

HH) PML-RAR $\alpha$ ,

II) E2A-PBX1.

It is noted that to the extent that the gene families listed in claims 12 and 15 may encompass species not listed above, Applicant may elect a single species from the recited gene families that is supported by the specification.

The species are independent or distinct because each oncogene is structurally and functionally different, resulting in fish with different structure, function and uses.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-23,25-34,36-58 and 60-73 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

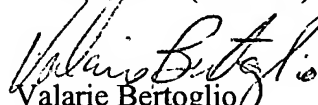
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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Valarie Bertoglio  
Examiner  
Art Unit 1632